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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,279	07/18/2001	Kazumi Iijima	K0208-013	5027

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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT PAPER NUMBER

1772

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/647,279	<b>Applicant(s)</b> IIJIMA, KAZUMI	
	<b>Examiner</b> Walter B Aughenbaugh	<b>Art Unit</b> 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004 and 09 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgement of Applicant's Amendments***

1. The amendments made in claims 1, 3 and 5 in the Amendment filed October 27, 2004 (Amdt. C) have been received and considered by Examiner.
2. New claims 7-9 presented in Amdt. C have been received and considered by Examiner.

### ***WITHDRAWN REJECTIONS***

3. The 35 U.S.C. 112 rejection of claims 1 and 3 made of record in paragraph 10 of the previous Office Action mailed April 9, 2004 has been withdrawn due to Applicant's amendments in Amdt. C.

### ***REPEATED REJECTIONS***

4. The 35 U.S.C. 102 rejection of claims 1 and 5 made of record in paragraph 11 of the previous Office Action mailed April 9, 2004 has been repeated for the reasons previously made of record and for the following reasons that address the amendments in claims 1 and 5 in Amdt. C: in regard to claim 1, a part of an inner surface of the luer lock portion has a roughened surface because the teeth (item 48) of the ears (item 34) are located at an inner surface of the luer lock portion (see Fig. 1 and 2). In regard to claim 5, the valleys between the peaks of the teeth (item 48) are indentations. The recitation "formed by blast treatment" is a method limitation that has not been given patentable weight since the method of forming the syringe barrel is not germane to the issue of patentability of the syringe barrel itself.
5. The 35 U.S.C. 103 rejection of claim 3 made of record in paragraph 12 of the previous Office Action mailed April 9, 2004 has been repeated for the reasons previously made of record,

Art Unit: 1772

taking into account the reason that addresses the amendments in claim 1 in Amdt. C provided above.

***NEW REJECTIONS***

***Claim Rejections - 35 USC § 112***

6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 3 both recite a roughened surface: the roughened surface that is recited in claim 7 cannot be ascertained (the roughened surface recited in claim 1 or the roughened surface recited in claim 3?).

***Claim Rejections - 35 USC § 103***

7. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al.

In regard to claim 7, Moncada et al. teach the syringe barrel as discussed above in regard to claim 3. The roughened surface of the luer lock portion includes indentations because the valleys between the peaks of the teeth (item 48) are indentations. The recitation “formed by blast treatment” is a method limitation that has not been given patentable weight since the method of forming the syringe barrel is not germane to the issue of patentability of the syringe barrel itself.

In regard to claim 8, Moncada et al. teach the syringe barrel as discussed above in regard to claim 1. Teeth (item 48) are not a required component of the ears (item 34) of Moncada et al. (col. 4, lines 59-61). Moncada et al. teach a Luer lock connector having ears (item 122) on the male Luer lock portion of the needle mount (item 94) and threads (item 124) on the female Luer lock portion (item 118) (col. 6, lines 7-16 and Fig. 5). Moncada et al. teach that the threaded

Art Unit: 1772

engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23). The portion of the female Luer lock portion (item 118) that has threads (item 124) corresponds the outer cylinder as claimed; Moncada et al. therefore teach that the inner peripheral surface of the outer cylinder contains a helically continuous screw thread.

Moncada et al. fail to explicitly teach that only the inner peripheral surface of the outer cylinder has a roughened surface.

However, since Moncada et al. teach that teeth or any other type of roughened surface increases frictional engagement between the component comprising the roughened surface and another component and that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23), one of ordinary skill in the art would have recognized to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed teeth or any other type of roughened surface on only the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed teeth or any other type of roughened surface on only the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the

Art Unit: 1772

cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al. in view of Porfano et al.

Moncada et al. teach the plastic syringe barrel as discussed above. Moncada et al. fail to explicitly teach that the syringe barrel is made of cyclic polyolefin resin. Porfano et al., however, teach a syringe barrel (item 12) that is made of cyclic polyolefin copolymer resin (col. 6, lines 48). Porfano et al. teach that cyclic polyolefin copolymers are suitable plastics to use as the syringe barrel material since cyclic polyolefin copolymers typically do not require a clarifying agent (col. 6, lines 46-48). Therefore, one of ordinary skill in the art would have recognized to use cyclic polyolefin copolymer resin as the material of the syringe barrel of Moncada et al. since cyclic polyolefin copolymer resin is a notoriously well known material for syringe barrels as taught by Porfano et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used cyclic polyolefin copolymer resin as the material of the syringe barrel of Moncada et al. since cyclic polyolefin copolymer resin is a notoriously well known material for syringe barrels as taught by Porfano et al.

#### ***ANSWERS TO APPLICANTS ARGUMENTS***

9. Applicant's arguments regarding the 35 U.S.C. 102 rejection of claim 1 as anticipated by Moncada et al. presented on pages 4-5 of Amdt. C have been fully considered but are not persuasive.

Art Unit: 1772

Applicant states that the combination of item 84 and adapter 80 is not a syringe barrel because Moncada et al. refers only to item 84 as a syringe barrel (such as in line 50 of col. 5). However, the combination of item 84 and adapter 80 constitutes a syringe barrel in the instance where the adapter, item 80, is “attached to a hypodermic syringe as a unit” (col. 8, lines 27-29) such that “a generally continuous surface is present at the junction of the syringe barrel 84 and the adapter 80” (col. 5, lines 50-52 and Fig. 5). Since the combination of item 84 and adapter 80 constitutes a syringe barrel in the instance cited above, Applicant’s argument that “Moncada et al. teach that the adapter invention is mounted on an unmodified syringe” is irrelevant. Applicant states that Moncada et al. teach that there is a gap between the barrel 84 and the adapter 80 at col. 5, lines 55-63, but Moncada et al. teach that “a gap may be present... between the barrel and the adapter” at col. 5, lines 59-61, not that a gap between the barrel 84 and the adapter 80 is required. Moncada et al. teach that there is no gap between the barrel 84 and the adapter 80 in the embodiment where “a generally continuous surface is present at the junction of the syringe barrel 84 and the adapter 80... to prevent catching or engaging of [a] sleeve engaging means in the gap between the barrel 84 and the adapter 80” (col. 5, lines 50-55).

Pertinent components of Moncada et al. read on the respective components claimed in claim 1 as explained in paragraph 11 of the previous Office Action mailed April 9, 2004. Since the combination of item 84 and adapter 80 constitutes a syringe barrel in the instance cited above, Applicant’s argument that “Moncada teaches away from modifying the syringe, or any portion thereof” is irrelevant.

Applicant’s argument that “the teeth on the ears of the Moncada et al luer lock do not address the problem solved by the roughened surface of the luer lock portion of Claim 1” is

Art Unit: 1772

irrelevant because the problem solved by the claimed structure is irrelevant in an anticipation rejection. Applicant argues that “any luer locks – and teeth formed thereon – are external to the syringe barrel”, but since the combination of item 84 and adapter 80 constitutes a syringe barrel in the instance cited above, the luer locks of Moncada et al. and the teeth of Moncada et al. are a part of the syringe barrel.

10. Applicant’s arguments regarding the 35 U.S.C. 103 rejection of claim 3 over Moncada et al. presented on page 5 of Amdt. C have been fully considered but are not persuasive. Applicant argues that “Moncada et al. does not teach or suggest that roughening the surface of the screw thread or the surface of the screw root portion improves engageability of an extension tube or like device...”, but the 35 U.S.C. 103 rejection of claim 3 does not state that roughening the surface of the screw thread or the surface of the screw root portion would improve “engageability of an extension tube or like device”.

11. Applicant’s arguments regarding the 35 U.S.C. 102 rejection of claim 5 as anticipated by Moncada et al. presented on pages 5-6 of Amdt. C are moot since the recitation “includes indentations” added to claim 5 in Amdt. C is addressed in paragraph 4 of this Office Action.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after



Art Unit: 1772

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh  
12/28/04

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